

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)
)
)
THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
)
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9041

Bartle, J.

April 5, 2013

Nancy L. Femmer ("Ms. Femmer" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Douglas E. Femmer, Ms. Femmer's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or
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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Randall G. Johnson, M.D. Based on an echocardiogram dated February 17, 2003, Dr. Johnson attested in Part II of Ms. Femmer's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%.⁴ Based on

3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Dr. Johnson also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$512,025.⁵

In the report of claimant's echocardiogram, the reviewing cardiologist, John B. Baird, M.D., F.A.C.C., stated that claimant had "[m]ild to moderate mitral regurgitation," which he measured at 21%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In October, 2005, the Trust forwarded the claim for review by Lawrence S. Mendelson, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Mendelson concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Mendelson explained:

The measurements of the RJA on the tape include substantial areas of low flow (blue), which is non-regurgitant flow. Thus, the RJA/LAA ratio calculated, 21%, is too high,

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

since the numerator (RJA) is too high. I get a maximum ratio of 15%. At worst, this [mitral regurgitation] is mild. It would be unreasonable to conclude moderate [mitral regurgitation].

Based on the auditing cardiologist's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Ms. Femmer's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted a letter from Alan R. Maniet, D.O., F.A.A.I.M., who stated that claimant had moderate mitral regurgitation with an RJA/LAA ratio of 22%. In support of this finding, Dr. Maniet attached two still frames from the echocardiogram, which purportedly demonstrated moderate mitral regurgitation. Claimant also argued that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because it was consistent with the finding of Dr. Baird, who performed claimant's echocardiogram under the Trust's Screening Program.⁷ In addition, claimant asserted that

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Femmer's claim.

7. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement). In contest, claimant also submitted a copy of her Gray Form. Under the
(continued...)

the attesting physician's opinion should be accepted unless it is "extreme or excessive." Claimant further contended that "[q]uantifying the level of regurgitation shown on an echocardiogram is inherently subjective."⁸ Claimant also suggested that the Trust was not properly applying the reasonable medical basis standard established in the Settlement Agreement. Finally, Ms. Femmer argued that Dr. Mendelson simply substituted his own opinion for that of the attesting physician and failed to follow the instructions given during the auditing cardiologist's training that "[mitral regurgitation] is considered to be present if blue, green, or mosaic signals are seen originating from the mitral valve and spreading into the [left atrium] during systole."⁹

7. (...continued)

Settlement Agreement, the Gray Form was used to report on the results from the Screening Program. See id. §§ IV.C.4.a.(8), VI.C.2.f. In the Gray Form, Dr. Baird indicated that claimant's echocardiogram demonstrated moderate mitral regurgitation and in a handwritten note stated, "[W]as just 21% of area."

8. In support of this argument, claimant referenced excerpts of depositions of five (5) physicians from other proceedings. None of the testimony submitted by claimant, however, specifically addressed Ms. Femmer's echocardiogram.

9. Claimant also asserted that the Trust should ensure that its auditing cardiologists do not have any "biases" against claimants. As there is no evidence that the auditing cardiologist had a "bias," this issue is irrelevant for resolution of this claim. Similarly, claimant also referenced, without any substantive discussion, a number of filings in MDL 1203. As claimant has not attempted to establish how those filings entitle her to Matrix Benefits, they are not pertinent to the disposition of this show cause claim.

The Trust then issued a final post-audit determination, again denying Ms. Femmer's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Femmer's claim should be paid. On May 11, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6264 (May 11, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on September 8, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹⁰ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare

10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Femmer reasserts the arguments that she made in contest. In addition, claimant contends that it is not uncommon for two cardiologists to review the same echocardiogram and to find different levels of regurgitation. According to claimant, "Neither diagnosis is correct or incorrect; both fall within the realm of having 'a reasonable medical basis.'" Finally, claimant asserts that Dr. Maniet's visual evidence excludes low velocity flow and provides a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation.

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard. The Trust also disagrees with claimant's interpretation of the training materials and argues that blue flow only constitutes mitral regurgitation when it originates from the mitral valve and spreads into the left atrium during systole. According to the Trust, the blue flow relied upon by claimants' cardiologists does not meet this requirement. The Trust also asserts that Dr. Maniet's RJA/LAA ratio measurement of 22% is "patently inconsistent" with his finding that the planimetry of the RJA on claimant's echocardiogram, which resulted in an RJA/LAA ratio of 21%, is "slightly generous."

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Vigilante determined that:

A thin central jet of mitral regurgitation was noted in the parasternal long axis view. Visually, mild mitral regurgitation was noted in the apical views. I digitized the cardiac cycles in the apical two chamber and four chamber views. I was able to accurately planimeter the RJA in the mid portion of systole. The largest RJA was 2.8 cm² found in the apical four chamber view. The RJA was less than 2.5 cm² in the apical two chamber view. I was able to accurately determine the LAA in this study. The LAA was 19.1 cm². Therefore, the largest RJA/LAA ratio was less than 15%. The RJA/LAA ratio never approached 20%. The majority of RJA/LAA ratios were less than 12%. There was one supposed RJA measured by the sonographer. This

measurement of 3.88 cm² was not representative of mitral regurgitation and included a great deal of low velocity and non-mitral regurgitant flow. The sonographer measured a LAA of 18.08 cm². This measurement was an off axis view of the left atrium and was inappropriately small. The inaccurate sonographer RJA/LAA ratio is calculated at 21% which is the same ratio as documented by Dr. Baird on his formal echocardiogram report. I reviewed Dr. Maniet's screen shot of his planimetry of the supposed RJA. His RJA calculation was 4.08 cm². This is an inaccurate measurement of the RJA seen in real-time on the actual echocardiogram tape. His calculation included a great deal of low velocity and non-mitral regurgitant flow. Dr. Maniet's screen shot demonstrating an LAA of 18.8 cm² is very similar to my accurate measurement of 19.1 cm².

In response to the Technical Advisor Report, claimant argues that the requirement that mitral regurgitation be seen in real time or that it is inappropriate to measure the single largest mitral regurgitation jet are inconsistent with the Weyman text.¹¹ In addition, claimant contends that submission of the

11. Claimant also included with her response to the Technical Advisor Report a "counter-report" by Dr. Maniet. Pursuant to Audit Rule 34, the Special Master advised Ms. Femmer that Dr. Maniet's supplemental report could not become part of the Show Cause Record. Thereafter, claimant filed a motion to have this additional report included in the Show Cause Record. According to claimant, in his supplemental report, Dr. Maniet disputed the Technical Advisor's finding that "he had included 'a great deal of low velocity and non-mitral regurgitant flow,'" and he attached citations to and excerpts from several medical texts referenced in the Settlement Agreement or authored by physicians familiar with these proceedings. Claimant argued that depriving her of the opportunity to address these findings "is arbitrary, unfair, a violation of due process, and nonsensical."

Pursuant to Audit Rule 34, there is no procedure by which
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entire record of her claim to the Technical Advisor, rather than only the medical information, "could do nothing but create bias against the claimant."¹²

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, we disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include:

11. (...continued)

Dr. Maniet's supplemental report can become part of the Show Cause Record. See PTO No. 8402 n.13. In any event, the auditing cardiologist, Dr. Mendelson, reviewed claimant's echocardiogram and also observed that "[t]he measurements of the RJA on the tape include substantial areas of low flow (blue), which is non-regurgitant flow." Although claimant was permitted to, and did, submit a response by Dr. Maniet to the audit findings, he did not dispute Dr. Mendelson's conclusions. In addition, at that time, neither claimant nor Dr. Maniet referenced the additional medical texts. Moreover, even if we were to consider Dr. Maniet's supplemental report, as explained infra, we repeatedly have held that a claimant may not rely on measurements that include low velocity flow or that are not representative of the level of regurgitation present on the subject echocardiogram. Here, this is what Ms. Femmer is attempting to do. For all of these reasons, we will deny claimant's motion.

12. As with Ms. Femmer's claim of bias by the auditing cardiologist, there is no evidence that the Technical Advisor had a "bias." Thus, this issue is irrelevant for resolution of Ms. Femmer's claim.

(1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

We also have rejected attempts by claimants to rely on still frame images documented on the echocardiogram tape that were not representative of the level of mitral regurgitation present on the particular study. See, e.g., PTO No. 8659 at 10 (Aug. 8, 2011). As we explained, "'[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of regurgitation are representative of the level of regurgitation throughout an echocardiogram.'" Id. (quoting PTO No. 6997 at 11 (Feb. 26, 2007)); see also In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 543 F.3d 179, 187 (3d Cir. 2008). "'To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which

would be contrary to the intent of the Settlement Agreement.'"

Id. (quoting PTO No. 6997 at 11).¹³

Here, Dr. Mendelson reviewed claimant's echocardiogram and determined that the amount of mitral regurgitation was exaggerated because "the measurements of the RJA on the [echocardiogram] tape include substantial areas of low flow (blue), which is non-regurgitant flow."¹⁴ Similarly, Dr. Vigilante determined that the RJA measurement by the sonographer "was not representative of mitral regurgitation and included a great deal of low velocity and non-mitral regurgitant flow." Dr. Vigilante also determined that the LAA measurement "was an off axis view of the left atrium and was inappropriately small."

Although claimant submitted the report of Dr. Maniet, Dr. Maniet does not refute these findings. Instead, he acknowledged that "the measurements of the mitral regurgitant jet as noted by the technician on the study tape appeared to be slightly generous." In addition, Dr. Vigilante reviewed the still frames Dr. Maniet submitted in support of his conclusion

13. We thus reject claimant's arguments that Dr. Mendelson's review was contrary to the training of auditing cardiologists we approved in PTO No. 2825 (Apr. 7, 2003).

14. For this reason as well, we disagree with claimant that the conflict between the attesting physician and the auditing cardiologist is due to the "subjective nature of echocardiography." Nor has Dr. Mendelson merely substituted his opinion for that of the attesting physician. Instead, Dr. Mendelson found that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation.

that claimant's echocardiogram demonstrated moderate mitral regurgitation. Dr. Vigilante observed, "[Dr. Maniet's] RJA calculation was 4.08 cm². This is an inaccurate measurement of the RJA seen in real-time on the actual echocardiogram tape. His calculation included a great deal of low velocity and non-mitral regurgitant flow." Such unacceptable practices by claimant's physicians cannot provide a reasonable medical basis for the Green Form representation that claimant suffered from moderate mitral regurgitation.

Finally, we reject claimant's assertion that she is entitled to Matrix Benefits because the echocardiogram that forms the basis of the claim was conducted in the Screening Program for Fund A Benefits under the Settlement Agreement. See Settlement Agreement § IV.A. Claimant's reliance on the echocardiogram obtained as a result of the Screening Program is misplaced. The Settlement Agreement clearly provides that the sole benefit a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662, which mandates a 100% audit requirement for all claims for Matrix Benefits. See PTO No. 2662 at 13 (Nov. 26, 2002). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Femmer's claim for Matrix Benefits and the related derivative claim submitted by her spouse.